

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
NORTHEASTERN DIVISION**

EDWIN R. BANKS,)
Plaintiff,) Civil Action No. 5:20-CV-0565-LCB
v.)
ALEX M. AZAR, II, in his official)
capacity as Secretary of the)
U.S. Department of Health and)
Human Services,)
Defendant.)

)

**DEFENDANT'S CROSS-MOTION FOR SUMMARY JUDGMENT AND IN
OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT
AND BRIEF IN SUPPORT THEREOF**

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I. INTRODUCTION

Plaintiff has been diagnosed with glioblastoma multiforme (“GBM”), a type of brain cancer. This case involves judicial review of the denial of Medicare claims for certain months of tumor treatment field therapy (“TTFT”) for Plaintiff’s GBM.¹ Plaintiff raises a single issue on appeal: whether the Secretary of the Department of Health and Human Services (“Secretary” or “Secretary of HHS”) is *forever* collaterally estopped from denying Plaintiff’s TTFT claims because one administrative law judge (“ALJ”) allowed coverage for certain months of TTFT. But Plaintiff is wrong on the law: there is no collateral estoppel here.

The ALJ decision that Plaintiff relies on to invoke collateral estoppel against the Secretary was rendered after the ALJ decision under review in the instant matter. As the ALJ that issued the decision under review could not have possibly considered a latter issued decision, collateral estoppel cannot be invoked against the Secretary in this matter.

Moreover, the doctrine of collateral estoppel does not apply to these kinds of administrative decisions, and attempting to apply it would be inconsistent with the design of the Medicare program. Plaintiff is asking that a non-precedential decision from one ALJ forever estop the Secretary from denying claims for TTFT

¹ Plaintiff is not financially responsible for paying for the TTFT claims at issue if Medicare does not cover it. *See infra* § III.

for Plaintiff. Plaintiff relies on *Astoria Fed. Savings & Loan Ass'n v. Solimino*, 501 U.S. 104 (1991), which held that an administrative decision regarding an age discrimination claim did *not* have preclusive effect because to apply collateral estoppel would be against Congress' intent in enacting the relevant statute. Giving preclusive effect to ALJ decisions would also interfere with the Secretary's discretion to permit case-by-case adjudication of Medicare claims. *See Heckler v. Ringer*, 466 U.S. 602, 617 (1984). Plaintiff fails to cite any cases on point, yet a number of circuits have followed the Supreme Court's reasoning and rejected similar attempts to bind federal agencies to non-precedential decisions in administrative appeals.

In addition, to permit collateral estoppel would run contrary to the Medicare statute's presentment and channeling requirements. Moreover, even if there was no bar to collateral estoppel, Plaintiff has failed to meet all four required elements. The issues in the ALJ decisions are not the same because the coverage determinations are each limited to specified time periods. The same issues were not actually litigated because the ALJ decision specifies that it applies only to the specific claims for Medicare coverage before him. In addition, because of limits on when the Secretary can appear in ALJ hearings, the Secretary did not have a full

and fair opportunity to litigate the issues. Plaintiff has forfeited any other issues for judicial review.²

For all these reasons, summary judgment should be granted in the Secretary's favor and Plaintiff's motion should be denied.

II. STATUTORY AND REGULATORY BACKGROUND

A. “Reasonable and Necessary” Medicare Expenses

Medicare is a federal health insurance program for the elderly and the disabled. For a medical service to be covered by Medicare, it must fit within a benefit category established by the Medicare statute.

This case concerns Medicare Part B, which extends coverage to certain types of durable medical equipment (“DME”) for qualified recipients. 42 U.S.C. §§ 1395k(a), 1395x(s)(6); 42 C.F.R. Part 410. Almost all Medicare coverage determinations, including those in this case, are subject to 42 U.S.C. § 1395y(a)(1)(A), which excludes certain items from coverage: “no payment may be made under . . . part B . . . for any expenses incurred for items or services[] which . . . are not reasonable and necessary for the diagnosis or treatment of illness

² Plaintiff's motion abandons any arguments other than collateral estoppel. *See* Plaintiff's brief (Pl. Br.) Therefore, Plaintiff has waived all other arguments. *See Sepulveda v. U.S. Att'y Gen.*, 401 F.3d 1226, 1228, n.2 (11th Cir. 2005) (“When an appellant fails to offer argument on an issue, that issue is abandoned.”).

or injury or to improve the functioning of a malformed body member” Unless there is an exception, this bar applies “[n]othwithstanding any other provision” of the Medicare statute. *Id.* The Centers for Medicare & Medicaid Services (“CMS”), which administers the Medicare program for the Secretary, has interpreted “reasonable and necessary” to mean that an item or service must be safe and effective, medically necessary and appropriate, and not experimental in order to qualify for reimbursement. *See Medicare Program Integrity Manual (“MPIM”)* § 13.5.4.³

To administer the “reasonable and necessary” standard, the Secretary employs a range of tools, from regulations to manuals. In choosing among these options, the Secretary is not required to promulgate regulations or policies that, “either by default rule or by specification, address every conceivable question” that may arise. *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 96 (1995). The Secretary may articulate “reasonable and necessary” standards through formal regulations that have the force and effect of law throughout the administrative process. *See* 42 U.S.C. §§ 1395hh; 1395ff(a)(1). The Secretary may also issue National Coverage Determinations (“NCDs”) “with respect to whether or not a

³ The MPIM is available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf>. The MPIM “is a compilation of guidelines which CMS issues to instruct Medicare contractors on how to conduct medical review of Medicare claims submitted by Medicare providers and suppliers for payment.” *Erringer v. Thompson*, 371 F.3d 625, 628 (9th Cir. 2004).

particular item or service is covered nationally.” 42 U.S.C. § 1395ff(f)(1)(B); *see also* 42 C.F.R. §§ 400.202, 405.1060.

B. Enforcement of the “Reasonable and Necessary” Standard Through Local Coverage Determinations

The Secretary has delegated to CMS broad authority to determine whether Medicare covers particular medical services. *See* 42 U.S.C. §§ 1395y(a), 1395ff(a), (f). CMS, in turn, contracts with Medicare Administrative Contractors (“MACs”), such as CGS Administrators in this case. 42 U.S.C. § 1395kk-1. A MAC makes coverage determinations, issues payments, and develops local coverage determinations (“LCDs”) for the geographic area it serves, *see* 42 U.S.C. § 1395ff(f)(2)(B), in accordance with the reasonable and necessary provisions of § 1395y(a)(1). *See* 42 U.S.C. §§ 1395kk-1(a)(4), 1395ff(f)(2)(B). An LCD is binding only on the MAC that issued it. *See* 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II).

In developing LCDs, a MAC follows program guidance. The MPIM requires that an LCD specify when “an item or service is considered to be reasonable and necessary.” MPIM § 13.5.4. A MAC develops an LCD by considering the medical literature, the advice of local medical societies and medical consultants, public comments, and comments from the provider community. MPIM §§ 13.2.3, 13.5.2.1, 13.5.3, 13.5.5; 66 Fed. Reg. 58,788 (Nov. 23, 2001). The MAC also follows detailed procedures for issuing new or revised LCDs, including engaging in a comment-and-notice period, soliciting feedback and

recommendations from the medical community, and presenting the policy in meetings of stakeholders. MPIM § 13.2.1.

C. The LCD for TTFT Devices

In April 2011, the Food and Drug Administration approved the marketing of the NovoTTF-100A device (later rebranded Optune), manufactured by Novocure, for the treatment of GBM. AR at 1291. Following an open meeting and solicitation of public comments, in August 2014, the Medicare program's DME MACs issued the original LCD for TTFT. *Id.* “The DME MACs determined that, based on the strength and quality of the evidence available at that time, TTFT was not reasonable and necessary for the treatment of GBM.” *Id.* This LCD stated that “Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.” AR at 1261. This LCD remained in effect during the dates of service for the Medicare claims at issue in the instant matter. *Id.*

In 2018, Novocure requested that the DME MACs approve Medicare payment of TTFT for newly diagnosed GBM. AR at 1291. Effective September 1, 2019, the LCD was revised to permit coverage for newly diagnosed GBM and continued coverage for newly diagnosed GBM beyond the first three months of therapy in certain circumstances. AR at 1286-87.

D. Medicare Claim Appeals

In order to challenge a denial of a Medicare claim, a beneficiary must pursue several levels of administrative appeal before he may come before a district court.

See generally 42 U.S.C. § 1395u(a); 42 C.F.R. § 405.904. First, the beneficiary seeks a redetermination from the MAC. 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. §§ 405.920, 405.940. Next the beneficiary seeks reconsideration by a qualified independent contractor (“QIC”) 42 U.S.C. § 1395ff(b)(1)(A), 1395ff(c); 42 C.F.R. §§ 405.960, 405.968(c)(1). The next level of review is a hearing before an ALJ, who issues a decision based on the evidence presented at the hearing or otherwise admitted into the record. 42 U.S.C. § 1395ff(b)(1)(A), 1395ff(d); 42 C.F.R. §§ 405.1000-02, 405.1042, 405.1046.

The administrative process ends in a review of the ALJ’s decision by the Medicare Appeals Council (“Council”). 42 U.S.C. § 1395ff(b)(1)(A), (d)(2); 42 C.F.R. §§ 405.1100, 405.1122. If the Council does not render a decision within a specified time frame, a beneficiary may request elevation of his appeal to district court. 42 C.F.R. § 405.1132. The Council’s decision (or the ALJ decision, if there is no review by the Council) represents the final decision of the Secretary for purposes of administrative exhaustion. 42 U.S.C. § 1395ff(b)(1)(A), (d)(2)(A); 42 C.F.R. §§ 405.1048, 405.1130, 405.1136.

The beneficiary is entitled to review of the Secretary's decision in the district court "as is provided in [42 U.S.C. §] 405(g)." 42 U.S.C. § 1395ff(b)(1)(A). Under review, the Secretary's findings of fact "if supported by substantial evidence, shall be conclusive." 42 U.S.C. § 405(g).

E. Advanced Beneficiary Notices

If Medicare coverage is denied, Medicare will nevertheless pay the claim if neither the supplier nor the beneficiary knew or could reasonably have been expected to know that the item would not be covered. 42 U.S.C. § 1395pp; 42 C.F.R. § 411.400(a). The supplier can shift the risk of non-coverage to the beneficiary by providing him with written notice ("Advance Beneficiary Notice") of the specific reason why the item probably will not be covered. 42 C.F.R. § 411.404(b).

III. FACTUAL AND PROCEDURAL BACKGROUND

This case arises from the denial of Plaintiff's claims for Medicare coverage of certain months of TTFT using the Optune system. On June 3, 2019, ALJ Bruce Kelton entered an order denying Plaintiff's claims for TTFT with dates of service in January, March, and April 2018. AR at 1251-1262. ALJ Kelton found that there was no evidence that Novocure required Plaintiff to sign an Advanced Beneficiary Notice, and Plaintiff was not financially liable for charges for the denied claims. AR at 1262. Plaintiff has fully exhausted his administrative

remedies: the ALJ’s decision became final when the Council did not issue a decision within 90 days of Plaintiff’s request for review, and Plaintiff requested escalation to the District Court. AR at 1263.

Plaintiff requests that the Court “enter an order finding that the Secretary is collaterally estopped from relitigating whether TTFT treatment for Plaintiff is a covered benefit.” Compl. at 14. Plaintiff relies on the decision of another ALJ, Jeffery Gulin, issued on June 6, 2019, to support his collateral estoppel argument. AR at 1273-1279. ALJ Gulin found that Plaintiff was entitled to coverage for TTFT for certain months. *Id.*

IV. STANDARD OF REVIEW

Judicial review of the Secretary’s final decision is limited to whether the Secretary’s final decision comports with applicable law and is supported by substantial evidence. *See* 42 U.S.C. § 1395ff(b), incorporating 42 U.S.C. § 405(g)). Substantial evidence is “more than a scintilla, but less than a preponderance.” *Richardson v. Perales*, 402 U.S. 389, 401 (1971). In conducting its review, the court “may only scrutinize the record.” *Leggett v. Chater*, 67 F.3d 558, 564 (5th Cir. 1995) (citations omitted).

V. ARGUMENT

A. Plaintiff's Evidence Outside of the Administrative Record Should be Excluded.

As a threshold matter, the Court's review must be limited to the certified Administrative Record. Plaintiff concedes that judicial review in this case is authorized by 42 U.S.C. § 405(g) (made applicable to the Secretary by 42 U.S.C. 1395ii), *see* Compl. at ¶ 5, Pl. Br. at 17, which states in pertinent part:

As part of the [Secretary]'s answer the [Secretary] shall file a certified copy of the transcript of the record including the evidence upon which the finding and decision complained of are based. The court shall have power to enter, *upon the pleadings and transcript of the record*, a judgment affirming, modifying, or reversing the decision of the [Secretary], with or without remanding the cause for a rehearing.

(emphasis added). Accordingly, Plaintiff's proffered evidence and argument that is outside of the Administrative Record do not fall within the scope of this case and should be excluded from the Court's consideration. *See Lovett v. Schweiker*, 667 F.2d 1, 3 (5th Cir. 1981) (“No evidence external to the administrative record is generally admissible in reviewing an administrative record pursuant to 42 U.S.C. § 405(g).”)⁴

⁴ Section 405(g) provides that the court may remand the case to the Secretary for additional evidence to be taken, only upon a showing that there is new evidence that is material and that there is good cause for Plaintiff's failure to incorporate the evidence into the record prior to these proceedings. Plaintiff has not made any such showing of good cause for failing to incorporate the evidence into the record, or that the evidence is material and would change the outcome of this matter. *See Hyde v. Bowen*, 823 F.2d 456, 459 (11th Cir. 1987) (new evidence is “material” if it is “relevant and probative so that there is a reasonable possibility that it would change the administrative result.”)

B. Collateral Estoppel Cannot Be Invoked Based on an ALJ Decision that Post-dates the Decision Under Review by This Court.

Plaintiff seeks to apply collateral estoppel by relying on an ALJ decision that was issued after the decision for which he seeks review in the instant matter. The decision of ALJ Kelton that is under review by this Court was issued on June 3, 2019. AR at 1251- 62. Plaintiff claims that the Secretary is collaterally estopped from denying his claims for coverage because Plaintiff received a favorable decision issued by ALJ Gulin on June 6, 2019. AR at 1273-79. Plaintiff contends that ALJ Gulin’s decision became final before the decision under review by this Court because the Secretary did not appeal ALJ Gulin’s decision. Plaintiff’s argument ignores the standard of review that controls this case.

As discussed *supra*, 42 U.S.C. § 405(g) provides that the court may enter a judgment “upon the pleadings and transcript of the record.” The court’s review is limited to the record that was before ALJ Kelton. The court’s function “in conducting this review is to determine whether there was a reasonable basis for the decision in light of the relevant legal standards and the facts known to the agency *at the time the decision was made.*” *Cross Terrace Rehab, Inc., LLC v. Sec’y, Dep’t of Health & Human Servs.*, 797 Fed. Appx. 503, 507 (11th Cir. 2020)(emphasis added) (*citing Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43, (1983); *Sierra Club v. Van Antwerp*, 526 F.3d 1353, 1360 (11th Cir. 2008)).

The later-issued decision by ALJ Gulin is in the Administrative Record solely because Plaintiff attached it with his request for escalation of his appeal to district court. AR at 1267-79. However, ALJ Kelton could not have possibly considered the later issued decision when he issued the decision under appeal in this case. Collateral estoppel cannot apply in this matter based on ALJ Gulin's decision.

The Court's inquiry should end here. There are additional reasons, however, why collateral estoppel cannot properly be invoked here. These reasons are discussed below.

C. Collateral Estoppel is Inapplicable in Medicare Claim Appeals.

While Plaintiff bases his collateral estoppel argument on one passage from the Supreme Court's decision in *Astoria*, Pl. Br. at 9-10,⁵ he omits the next paragraph of the decision, which explains, significantly, that preclusion cannot apply when there is a statutory purpose to the contrary: "Courts do not, of course, have free rein to impose rules of preclusion, as a matter of policy, when the interpretation of a statute is at hand[,] ... [and] the question is not whether administrative estoppel is wise but whether it is intended by the legislature."

⁵ In *Astoria*, the Court considered whether claimants alleging age discrimination under federal law are "collaterally estopped to re-litigate in federal court the judicially unreviewed findings of a state administrative agency made with respect to an age-discrimination claim." 501 U.S. at 106. The Court held that the state court's findings had no preclusive effect on federal proceedings. *Id.* Because the federal government was not a party, and the Court found the *absence* of estoppel, Plaintiff's cited language is dicta.

Astoria, 501 U.S. at 108; *see JSK v. Hendry County School Bd.*, 941 F.2d 1563 (11th Cir. 1991) (declining to apply doctrine of collateral estoppel when doing so would go against intent and purpose of statute at issue). Here, the Medicare statute and regulations indicate a clear intent to bar the application of collateral estoppel to ALJ decisions.

Plaintiff relies on several other cases for the assertion that collateral estoppel should apply to unreviewed ALJ decisions denying Medicare benefits, but they are inapposite. *See* Pl. Br. at 9. Plaintiff cites *B & B Hardware, Inc. v. Hargis Industries*, 575 U.S. 138 (2015), a matter that involved private parties, and one in which the Court did not consider whether the federal government may be bound by administrative decisions. Plaintiff cites *Continental Can Co. v. Marshall*, 603 F.2d 590 (7th Cir. 1979), which was decided well before *Astoria*, and therefore did not consider whether there was a statute prohibiting collateral estoppel. *See B & B Hardware*, 575 U.S. at 148 (applying *Astoria*'s rule that issue preclusion cannot be applied if there is a statute preventing it). *Bowen v. United States*, 570 F.2d 1311, 1319–20 (7th Cir. 1978) was decided pursuant to Indiana's collateral estoppel law and, in contrast to the statutes in this case, Indiana law specifically stated that a federal administrative agency decision finding violations of air safety rules also constituted a state law violation because the state law incorporated the federal standard.

In *Brewster v. Barnhart*, 145 F. App'x 542 (6th Cir. 2005), the court found that, under circumstances unique to Social Security disability appeals, an applicant (not the Government) was bound by an ALJ's earlier finding concerning the exertional level of the applicant's past work. *Id.* at 546-48. Plaintiff's additional citation to *Islam v. U.S. D.H.S.*, a case concerning the unique circumstances of immigration appeals is similarly unhelpful. *Islam v. U.S. D.H.S.*, 136 F. Supp. 3d 1088 (N.D. Cal. 2015). Among other things, the *Islam* court determined that the Immigration and Nationality Act permitted collateral estoppel of issues decided by an Immigration Judge in granting asylum. *Id.* at 1093-94. Additionally, unlike here, the other elements of collateral estoppel were actually met in *Islam*. *Id.* at 1091-93. Finally, in *Cannon v. U.S.*, 2019 WL 5550065 (S.D. Cal. Oct. 28, 2019), the court held that the plaintiff, not the Government, was bound by the decision of a Department of Labor ALJ pertaining to a workplace injury. The court found that the plaintiff did not cite to any statutes reflecting Congressional intent that the administrative decision could not be subject to issue preclusion. *Id.* at 5. Significantly, Plaintiff has cited no case in which collateral estoppel was applied to a Medicare coverage determination.

1. *The applicable Medicare regulations provide that ALJ decisions do not bind the Secretary in future cases.*

The Medicare statute and regulations bar the application of collateral estoppel to ALJ decisions. The Medicare regulations sharply distinguish between a narrow category of precedential decisions that are binding on future administrative appeals and the remainder of non-precedential decisions that are not binding. Only Council-level decisions even have the potential to become precedential, and this occurs only when they are so designated by the Chair of the Departmental Appeals Board. 42 C.F.R. § 401.109. These must be made available to the public, with personally identifiable information removed, with notice published in the Federal Register. 42 C.F.R. § 401.109(b). The decision is then given “precedential effect” and is binding on “all HHS components that adjudicate matters under the jurisdiction of CMS.” *Id.* § 401.109(c). The term “precedential effect” means that the Council’s:

- (1) Legal analysis and interpretation of a Medicare authority or provision is binding and must be followed in future determinations and appeals in which the same authority or provision applies and is still in effect; and
- (2) Factual findings are binding and must be applied to future determinations and appeals involving the same parties if the relevant facts are the same and evidence is presented that the underlying factual circumstances have not changed since the issuance of the precedential final decision.

Id. § 401.109(d). Accordingly, the term “precedential effect” is synonymous with a decision having binding or preclusive effect.

Here, no Council decision, much less one designated as precedential, has favorably decided any of Plaintiff’s claims. Accordingly, nothing in the Medicare statute or regulations binds the Secretary to approve Plaintiff’s TTFT claims. *See Almy v. Sebelius*, 679 F.3d 297, 310 (4th Cir. 2012) (finding that the Secretary could not have departed from prior precedent because there were no Council-level decisions finding that the device at issue was “reasonable and necessary” or “safe and effective”).

The regulations on LCDs offer further support that ALJ decisions are nonbinding and therefore collateral estoppel does not apply. Plaintiff’s collateral estoppel argument relies upon a favorable ALJ decision that departed from the LCD and approved TTFT treatment.⁶ However, an ALJ’s decision to depart from an LCD “applies only to the specific claim being considered and does not have precedential effect.” 42 C.F.R. § 405.1062(b) (emphasis added). The regulations reaffirm that only “[p]recedential decisions designated by the Chair of the Departmental Appeals Board in accordance with § 401.109 of this chapter, are binding . . .” 42 C.F.R. § 405.1063(c). “Nowhere does any policy or regulation suggest that the [Council] owes any deference at all to—much less is bound by—decisions of lower reviewing bodies addressing different disputes between

⁶ ALJs are not bound by LCDs, but are required to afford them “substantial deference.” 42 C.F.R. § 405.1062(a).

different parties merely because they pertain to the same device.” *Almy*, 679 F.3d at 310. Indeed, ALJ decisions are not even binding upon lower levels of administrative review, such as the QIC level of review. *See* 42 C.F.R. § 405.968(b)(1) (omitting ALJ decisions among the rulings that bind the QIC).

Giving preclusive effect to ALJ decisions would also run contrary to the Medicare statute, which provides that the Council must “review the case de novo.” 42 U.S.C. § 1395ff(d)(2)(B) (emphasis added); *see Porzecanski v. Azar*, 943 F.3d 472, 477 (D.C. Cir. 2019). “Because the review generally binds only the parties unless specifically designated as precedential, a favorable determination in one proceeding does not ensure that future claims will be approved.”). If a favorable ALJ ruling collaterally estopped the Council from denying a beneficiary’s claim for the same treatment, the Council could not perform a de novo review; instead, the Council would be bound to accept the ALJ’s conclusions. *See Almy*, 679 F.3d at 303 (concluding that Council’s obligation to undertake “de novo” review was “incompatible with [plaintiff’s] proffered notion that the [Council] is somehow obligated to defer to the outcomes of prior decisions below”).

The Medicare regulations direct that ALJ decisions are not to be accorded conclusive effect as they are non-precedential, and the Council’s de novo review provided by the Medicare statute means the Council is free to make an independent determination. Accordingly, the Medicare statute and regulations bar the

application of collateral estoppel to the decisions of ALJs. *See Astoria*, 501 U.S. at 111–12 (rejecting application of collateral estoppel to a federal statute because applying the principle would render a section of that statute superfluous).

2. *Applying collateral estoppel would interfere with the discretion and deference afforded to the Secretary to implement the Medicare statute.*

If ALJ decisions were deemed binding, they would also interfere with the deference and discretion afforded to the Secretary to implement the Medicare statute’s “reasonable and necessary” standard for coverage of items and services furnished to program beneficiaries. “[T]he choice made between proceeding by general rule or by individual, *ad hoc* litigation is one that lies primarily in the informed discretion of the administrative agency.” *SEC v. Chenery Corp.*, 332 U.S. 194, 203 (1947). The Medicare statute and regulations preserve “this discretion for the Secretary, leaving it to her judgment whether to proceed by implementing an NCD, by allowing regional contractors to adopt an LCD, or by deciding individual cases through the adjudicative process.” *Almy*, 679 F.3d at 303. The Supreme Court has foreclosed interference with this discretion, holding that “[t]he Secretary’s decision as to whether a particular medical service is ‘reasonable and necessary’ and the means by which she implements her decision, whether by promulgating a generally applicable rule or by allowing individual adjudication, are clearly discretionary decisions.” *Ringer*, 466 U.S. at 617.

As noted above, the Medicare regulations designate ALJ decisions as non-binding and non-precedential, which allows individual adjudication over Part B claims. Generally speaking, this inures to the benefit of Medicare beneficiaries, who, even after repeated denials of similar claims, will have a right of review on any subsequent claims. The application of collateral estoppel, therefore, is fundamentally inconsistent with individual adjudication of Part B claims. In Plaintiff's view, once a claim for benefits is approved, the Secretary would be estopped from ever denying a claim for the same treatment. Pl. Br. at 17. Individual adjudication would be impossible, because the earliest-in-time ALJ ruling would forever bind the Secretary. It is within the Secretary's discretion *not* to be bound by ALJ rulings. *See generally Ringer*, 466 U.S. at 607-08 (distinguishing between ALJ and Council-level decisions that "applied only to the claimants involved in that case and [were] not to be cited as precedent in future cases" and a subsequent formal administrative ruling by the Secretary that bound ALJs and the Council).

While Plaintiff fails to cite any cases on point, a number of appellate courts have rejected attempts to bind federal agencies to non-precedential decisions in lower-level administrative appeals. In *Almy*, a plaintiff asserted that Council decisions denying coverage for a medical device created a policy of denying treatment for that device. 679 F.3d at 299. The Fourth Circuit disagreed, noting

that “[t]he Secretary’s own regulations make clear that any policy implications in an adjudication do not have precedential effect. . . . The purported ‘policy’ in this case is nothing more than the accretion of individual decisions finding that the [device] does not meet the statutory requirements for coverage.” *Id.* at 303. The Fourth Circuit noted that Congress gave the Secretary discretion to “decide how to deal with hundreds of millions of Part B claims for coverage of thousands of devices every year.” *Id.* at 304. Likewise, this Court should reject Plaintiff’s attempt to elevate non-precedential ALJ opinions into binding coverage rules, which would “stultify the administrative process.” *See id.* (quoting *Cheney*, 322 U.S. at 202).

The Fourth Circuit noted that other circuits have concluded that “[t]here is no authority for the proposition that a lower component of a government agency may bind the decision making of the highest level . . . [E]ven if these cases were found to evince internal inconsistency at a subordinate level, the [agency] itself would not be acting inconsistently.” *Id.* at 310 (quoting *Community Care Found. v. Thompson*, 318 F.3d 219, 227 (D.C. Cir. 2003)). Along the same lines, the D.C. Circuit has emphasized its “well-established view that an agency is not bound by the actions of its staff if the agency has not endorsed those actions.” *Comcast Corp. v. FCC*, 526 F.3d 763, 769 (D.C. Cir. 2008) (citing cases). Instead, “a definitive and binding statement on behalf of the agency must come from a source

with the authority to bind the agency.” *Devon Energy Corp. v. Kemphorne*, 551 F.3d 1030, 1040 (D.C. Cir. 2008); *see, e.g., Freeman v. U.S. Dep’t of the Interior*, 37 F. Supp. 3d 313, 344-45 (D.D.C. 2014) (finding that “unappealed” ALJ rulings could not estop the United States because such rulings were not binding on the agency or even on other ALJs, and noting that the lack of appeal did not “elevate them to the level of a binding final agency action”).

The Ninth Circuit adopted the reasoning of *Almy*, reversing a district court decision that “incorrectly measured agency inconsistency across” ALJ decisions. *Int’l Rehab. Sci. Inc. v. Sebelius*, 688 F.3d 994, 1001 (9th Cir. 2012). Likewise, the Seventh Circuit recognized that lower-level decisions may conflict and do not bind the Secretary. *Abraham Mem’l Hosp. v. Sebelius*, 698 F.3d 536, 556 (7th Cir. 2012) (“The handful of prior Board decisions the Hospitals rely upon to purportedly show HHS’s long-standing policy are not determinative. Our precedent instructs that Board decisions are not the decisions of the Secretary or her Administrator and are not authoritative.”). The Fifth Circuit reached the same conclusion. *See Homan & Crimen, Inc. v. Harris*, 626 F.2d 1201, 1205 (5th Cir. 1980) (“[T]he decision of the [Provider Reimbursement Review Board] carries no more weight on review by the Secretary than any other interim decision made along the way in an agency where the ultimate decision of the agency is controlling.”).

The doctrine of collateral estoppel cannot transform an ALJ ruling from what it is, a decision by an intermediate-level tribunal that is binding only in a single case, to what it is not, an officially binding statement of policy by the Secretary. To do so would be contrary to the Medicare statute and regulations.

3. *Collateral estoppel is contrary to the Medicare Act's presentment and channeling requirements.*

To the extent that Plaintiff seeks to have the Secretary collaterally estopped as to future claims for TTFT, the D.C. Circuit recently held in *Porzecanski* that the Medicare statute prohibits a Medicare beneficiary from obtaining “prospective equitable relief mandating that HHS recognize his treatment as a covered Medicare benefit in all future claim determinations.” 943 F.3d at 475.

The facts in *Porzecanski* are similar to those in the instant case. *Porzecanski* suffered from a life-threatening condition with no known cure and started on an experimental regimen of a biological product. *Id.* at 476. After beginning treatment, the plaintiff remained symptom-free, and his physicians recommended that he continue the monthly treatment indefinitely. *Id.* at 476-77. After one of his Medicare claims was denied at the ALJ level and the Council did not render a decision within the required time frame, he sued for review by a district court. *Id.* at 477. Plaintiff sought declaratory and injunctive relief confirming his entitlement to Medicare coverage for the product and requiring the Secretary to provide Medicare benefits. *Id.*

The D.C. Circuit held that plaintiff could not “satisfy § 405(g)’s presentment requirement with respect to future claims because those claims have not yet arisen.” *Id.* at 482. Because Medicare claims can only be filed after the medical service has been furnished, and section 405(g) requires appeals from “decision[s]” of the Secretary, the presentment requirement could not be met: “[T]he Secretary has not decided [plaintiff’s] future claims because – to state the obvious – none has been submitted.” *Id.*

The court also rejected plaintiff’s request to *preclude* the Secretary from concluding that the claims on appeal were not covered by Medicare and were not medically necessary – the *identical* relief that Plaintiff seeks here. *Id.* at 482 (finding plaintiff’s “strained position” to be “at odds with Supreme Court precedent.”). In support, the D.C. Circuit relied on two Supreme Court decisions: *Ringer* and *Illinois Council*. In *Ringer*, “the Court held that § 405(g) barred a patient from obtaining declaratory and injunctive relief compelling the Secretary to conclude that his future surgery was ‘reasonable and necessary’ under the Medicare Act.” *Id.* (citing 466 U.S. at 620-21). Likewise, in *Illinois Council*, the Court again declared that a “claim for future benefits is a § 405(h) claim” and that “all aspects” of any future claim “must be channeled through the administrative process.” *Id.* (citing 529 U.S. at 12).

The D.C. Circuit concluded that “*Ringer and Illinois Council* directly foreclose [plaintiff’s] attempt to recast the requested relief as anything other than a claim for future benefits.” *Id.* at 483. Likewise, Plaintiff’s assertion that the Secretary is estopped from denying his future claims for TTFT “runs headlong into the Supreme Court’s instruction that ‘all aspects’ of a claim be first channeled through the agency.” *See id.* (quoting *Illinois Council*, 529 U.S. at 12). Plaintiff cannot leverage a favorable ALJ decision to estop the Secretary from denying “future claims for the same reasons.” *See id.* at 483-84.

D. The Elements of Collateral Estoppel are Not Met.

Even if collateral estoppel could be invoked in this case, the elements have not been met. As the party invoking collateral estoppel, it is Plaintiff’s burden to show that:

- (1) the issue at stake is identical to the one involved in the prior proceeding;
- (2) the issue was actually litigated in the prior proceeding;
- (3) the determination of the issue in the prior litigation must have been “a critical and necessary part” of the judgment in the first action; and
- (4) the party against whom collateral estoppel is asserted must have had a full and fair opportunity to litigate the issue in the prior proceeding.

Christo v. Padgett, 223 F.3d 1324, 1339 (11th Cir. 2000). As noted above, collateral estoppel cannot apply because the unfavorable ALJ decision on appeal here (dated June 3, 2019) *predates* the favorable ALJ decision (dated June 6, 2019) that Plaintiff attempts to use to establish collateral estoppel. Nor has Plaintiff carried his burden on the first, second, and fourth elements of collateral estoppel.

1. The issues are not identical.

First, the issues decided in Plaintiff's claim appeals were different, because each concerned whether TTFT was covered under Medicare for a *specific period in time*. *See* Pl. Br. at 4, ¶ 9; 5, ¶ 17. Notably, both the ALJ who denied Plaintiff's claim and the ALJ who approved another claim limited his respective "Conclusions of Law" to the coverage dates under appeal. *See* AR at 1262 (6/3/19 Unfavorable Decision) (denying coverage for dates of service of 1/15/2018, 3/12/2018 and 4/12/2018); AR at 1279 (6/6/19 Favorable Decision) (approving coverage "on the dates of service [February 2018, May 2018-December 2018, January 2019]"). Because the favorable ALJ decision did not adjudicate whether Medicare coverage existed for any other claims, much less the claims simultaneously on appeal before another ALJ, the first element of collateral estoppel is not present. *See, e.g., Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 435 F.3d 1356, 1361-62 (Fed. Cir. 2006) (declining to apply collateral estoppel where patent infringement involved two distinct time periods).

2. The same issue was not actually litigated.

As to the second element, again the differing time periods covered by each ALJ decision means that same issue was not actually litigated. The favorable decision explicitly limited the time period of the coverage decision, as do the Medicare regulations limiting the precedential effect of ALJs declining to follow

an LCD, 42 C.F.R. § 405.1062(b). AR at 1262, 1279. As such, Plaintiff cannot meet the second element. *See Donovan v. Fed. Clearing Die Casting Co.*, 695 F.2d 1020, 1022 (7th Cir. 1982) (issue not actually litigated when issue left expressly undecided by decision); *Interoceanica v. Sound Pilots*, 107 F.3d 86, 91–92 (2nd Cir. 1997) (issue not actually litigated or decided where prior decision explicitly stated it did not reach an issue); *California Communities Against Toxics v. EPA*, 928 F.3d 1041, 1052 (D.C. Cir. 2019) (finding issues not actually litigated where court stated it did “need not address” the issue).

3. The Secretary was not fully represented in the prior action.

Finally, the fourth element is not met because the Secretary’s opportunity to litigate is limited in Medicare coverage appeals. The Secretary has no opportunity to participate during the first (redetermination) and second (QIC) levels of the appeal process. *See* 42 C.F.R. §§ 405.948, 405.968. *See Genesis Health*, 798 F. Supp. 2d at 182 (“[I]f an intermediary finds coverage and pays a claim, there is never an administrative appeal, and the Secretary would have no knowledge of the intermediary’s decision nor opportunity to review those actions.”). The Secretary’s participation is also limited in ALJ appeals. When a beneficiary is unrepresented, the Secretary cannot be a party to the hearing, and thus has no opportunity to litigate. 42 C.F.R. § 405.1012(a). Furthermore, if the Secretary does not affirmatively elect to participate or become a party in ALJ proceedings,

the proceedings simply move forward without the Secretary's involvement. 42 C.F.R. §§ 405.1010(a), 405.1012(b). Although the Secretary may participate or become a party in ALJ hearings involving beneficiaries represented by counsel, it is impracticable for the Secretary to litigate hundreds of thousands of appeals annually. 42 C.F.R. §§ 405.1010(a), 405.1012; 82 Fed. Reg. 4974, 4976 (Jan. 17, 2017) (noting 650,000 pending ALJ appeals as of September 2016).

If the Secretary does not become a party to an ALJ hearing, the Secretary cannot appeal a favorable ruling to the Council. 42 C.F.R. §§ 405.1012, 405.1102(a)(1), (d). In other words, the Secretary would need to litigate every ALJ hearing in order to have the right to appeal any decisions favorable to the beneficiary. Therefore, as the Secretary's opportunity to appeal was also extremely limited, there was not a full and fair opportunity to litigate.

4. A lack of incentive to litigate ALJ decisions weighs against preclusion.

Courts have also recognized an exception to applying preclusion even where all the elements for estoppel are met. Where there is an incentive against extensively litigating smaller matters (because cost outweighs the size of the issue), it is unfair to allow the decisions in those smaller matters to have large preclusive effects. Such is the case here, where the Secretary's involvement in the litigation of every claim would be an inefficient use of resources better put towards the Medicare program. Unreviewed and nonprecedential ALJ decisions should not

be given preclusive effect, which would result in great cost to the Medicare Trust.

See Power Integrations v. Semiconductor Components Indus., 926 F.3d 1306, 1312, 1313 (Fed. Cir. 2019)(holding that the exception of “a lack of opportunity or incentive to litigate the first action” prevented preclusion where there was a disparity in incentives to appeal an issue); *Rawls v. Daughters of Charity of St. Vincent De Paul*, 491 F.2d 141, 148 (5th Cir. 1974) (no preclusive effect given to habeas corpus hearing finding involuntary hospitalization was illegal in subsequent suit against hospital for false imprisonment because the hospital “had far less incentive to contest the unlawfulness of the plaintiff’s detention than at present”).

5. *Even if collateral estoppel applied, it would have no force after the new LCD became effective on September 1, 2019.*

Even if collateral estoppel applied here, it would have no force after the new LCD became effective on September 1, 2019. Collateral estoppel generally will not apply when there has been a change in essential facts. *See Montana v. United States*, 440 U.S. 147, 159 (1979) (“It is, of course, true that changes in facts essential to a judgment will render collateral estoppel inapplicable in a subsequent action raising the same issues.”); *see also CSX Transp., Inc. v. Bhd. of Maint. of Way Emps.*, 327 F.3d 1309, 1318 (11th Cir. 2003) (“Because we have concluded that the facts in this case are materially different, . . . preclusive effect is inappropriate . . .”). Here, there was a significant change between the old LCD, which categorically denied coverage for TTFT, and the new LCD, which allowed

coverage of TTFT under certain circumstances. Accordingly, if Plaintiff were to prevail on collateral estoppel, the only decision that might be estopped would be the June 3, 2019 ALJ decision denying Plaintiff's claims for TTFT. Further preclusive or injunctive relief would not be warranted, because the new LCD has already been in place for a number of months now.

Along the same lines, the medical context of this case necessarily means that the controlling facts are constantly changing. Physicians do not prescribe treatment, no matter how potentially effective, *indefinitely* into the future. A treatment that may have been beneficial for a patient at one point in time could be ineffective or dangerous if continued (e.g., when a patient suffers serious side effects). Even if Plaintiff's medical history remained unchanged for two years, it would still be speculation to assume the facts would remain unchanged for any claim he might file in the future. For example, if Plaintiff filed claims for coverage, but the evidence showed that he was not actually using the device, Medicare should not be required to approve the claims. *See* AR at 1315 (current LCD requires that beneficiary "use TTFT for an average of 18 hours per day").

Because the controlling facts and law have changed, applying collateral estoppel would not benefit Plaintiff, who is not financially responsible for the claims on appeal. Meanwhile, a finding that favorable ALJ decisions have preclusive effect would have widespread, negative ramifications for the Medicare

program, and the many million Americans it serves. Because collateral estoppel is fundamentally inconsistent with the Medicare Program, the Court should grant summary judgment for the Secretary.

VI. CONCLUSION

For the foregoing reasons, the Secretary respectfully requests that the Court grant his motion for summary judgment and deny Plaintiff's motion
Respectfully submitted,

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